OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test
Information and Self-Assessment Tool
Maryland AIDS Administration, Baltimore MD

As many of you know, OraQuick ADVANCE® Rapid HIV-1/2 Antibody Tests is available in the State of Maryland. In an effort to expedite the education, training and distribution process for rapid testing, the Maryland AIDS Administration has compiled a short self-assessment tool. This self-assessment tool will help both you and the AIDS Administration determine whether or not the OraQuick ADVANCE® test will be right for your agency or organization. If you and your agency are interested in providing the OraQuick ADVANCE® test for your clients, please read the information below, fill out the questionnaire (*please type*), tear off pages 3 - 7, make copies for yourself and return the originals to Rob Lunn, MPA, AIDS Administration, 500 N. Calvert St. - 5th Floor, Baltimore, MD 21202 or fax to 410-333-4805 (or e-mail rlunn@dhmh.state.md.us).

INFORMATION ABOUT THE ORAQUICK ADVANCE® RAPID HIV-1/2 ANTIBODY TEST

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is the first FDA-approved test that provides results with 99.6% accuracy in as little as 20 minutes. Using either an oral swab or less than a drop of blood, the OraQuick ADVANCE® device can quickly and reliably detect antibodies for HIV-1/2, the virus that causes HIV in the United States. The ability to use an oral swab or only a drop of blood from a finger stick, may make HIV testing more acceptable to clients who are afraid of venipuncture techniques or who are venous compromised.

The simplicity of this test will allow OraQuick ADVANCE® to be used more easily in non-clinical settings where individuals may not be trained in phlebotomy and where infrastructure does not allow for handling and/or storage of blood specimens. This simple test, eliminates the need for preparation of a sample through use of specialized equipment. OraQuick ADVANCE® can be used by a wide variety of agencies, including non-traditional providers of HIV counseling, testing and referral (CTR) services. It can also be used in conjunction with outreach and field services (e.g., emergency departments, mobile van and other outreach events).

The convenience of this test is designed to fulfill three main purposes. First, to encourage individuals to get tested for HIV who may not have thought of or agreed to being tested before. Second, to increase the number of people who learn their HIV status. Third, to decrease the need for follow-up activities to locate clients who do not return for their HIV test results. These factors combined may help to prevent the spread of HIV, ensure the immediate access to services and/or treatment for those who are infected and reduce the amount of time associated with HIV CTR follow-up.

OraQuick ADVANCE® may also prove useful for pregnant women and for health professionals. The American Foundation for AIDS Research states that nearly 20% of all pregnant women do not know their HIV status at the time of delivery. OraQuick ADVANCE® would allow results to be obtained and treatment started if needed while the mother was still in labor. This action could substantially reduce the chance that the infant will become infected with HIV.

Additionally, many health care professionals experience accidental “needle sticks” every year. After a possible exposure, the use of a rapid test on a consenting client and the receipt of a negative test result may eliminate the practice of placing workers on post-exposure prophylactic medications unnecessarily.

DESCRIPTION OF THE ORAQUICK ADVANCE® RAPID HIV-1/2 ANTIBODY TEST

As mentioned above, OraQuick ADVANCE® has been approved for oral fluid, fingerstick and venipuncture whole blood along with a moderate complexity level test using plasma. The sample obtained on the test device is inserted into a special testing solution to begin processing. The result is visually readable in about 20 minutes. The materials contained in the master-shipping carton include a reusable test stand, subject information pamphlets, specimen collection loops and package inserts. Included in the divided test pouch are one developer solution vial, one test device and one absorbent packet (See Fig. 1). The materials that will be needed but that are not included in the kits are disposable gloves, sterile lancets, a timer or watch, antiseptic wipes, sterile gauze pads, and a biohazard disposal container. Additionally, quality control kits will need to be available at each site as there are very specific methods used to run quality control checks that ensure the tests are functioning properly. **These quality control kits require refrigeration.**

Fig. 1

Unused OraQuick ADVANCE® Rapid HIV-1/2 Antibody Tests should be stored unopened at 59-80º F (room temperature). There is no need to refrigerate the test kits. However, as mentioned above, the quality control kits will need to be refrigerated. Adequate storage space will therefore be needed, both in a closet or cabinet and in a refrigerator.

In addition, there are federal and state regulations that must be considered if you want to utilize OraQuick ADVANCE® The Clinical Laboratory Improvement Amendments of 1998 (CLIA) establishes quality standards for laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. CLIA requires that any facility examining human specimens for diagnosis, prevention, treatment of a disease or for assessment of health must register with the federal Centers for Medicare & Medicaid Services (CMS) and obtain CLIA certification.

Because the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is simple and accurate, the Food and Drug Administration (FDA) approved it as a waived test. Waived tests are determined to be easy to use and have little risk of an incorrect result. So far, more than 1,400 test systems have been waived. A Certificate of Waiver is one of four types of required certificates and is the type to request if you plan to conduct only waived tests, such as the OraQuick ADVANCE test.

Maryland has additional regulations that apply to laboratory testing, and requires a separate application to the state agency for regulations that apply specifically to HIV testing. These regulations require training to provide counseling, testing, and referral services, draw blood, and

perform the test. Before applying, you will have to consider these applicable requirements and then apply to receive the authority for testing.

IS RAPID HIV TESTING RIGHT FOR YOUR JURISDICTION?

In most cases, health departments or CBO's are likely to consider rapid HIV testing more appropriate for particular settings within an organization rather than for an organization as a whole. In general, if there are settings within your area where rates of return for test results are sub-optimal, rapid HIV testing may be a useful tool to improve these rates. Similarly, if there are communities at increased risk for HIV who are not currently availing themselves of HIV CTR services, rapid HIV testing may be one mechanism for encouraging use of these services. The CDC's *Revised Guidelines for HIV Counseling, Testing and Referral* provides technical guidance on the uses of testing technologies, including HIV rapid tests, and should be used to help determine the benefits of a particular technology within your jurisdiction (www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm).

SELF-ASSESSMENT TOOL

A variety of criteria will be considered when determining an initial pattern of distribution for OraQuick ADVANCE®. The primary factors that will be considered will be an area's HIV seroprevalence rates and the "rate of return" for test results. Based on current Maryland statistics, a guideline of at least a 1% HIV seroprevalence for both your jurisdiction and your organization *and* a return rate of less than 70% has been established to help determine if rapid testing is appropriate for your agency. Listed below are a series of questions that will be used to help both your agency and the AIDS Administration determine if rapid testing is appropriate for your jurisdiction at this time. Please answer the questions to the best of your ability. If you have any questions you may contact your Program Coordinator (Jenna Burt, MPH, Dana Herrod, BS, or Rob Marino, BA at 410-767-5018 or The CTR Team Leader, Rob Lunn, MPA, at 410-767-5035. You may attach additional sheets as needed (please label answers with the corresponding question number).

Organization/Agency: _____ Date: _____

Person completing form: _____ Phone: _____

1) What was the seroprevalence rate in your *jurisdiction* (i.e., County or City of Baltimore) for July 2003 through June 2004 (FY 04)?

2) What was the seroprevalence rate for your *organization* for July 2003 through June 2004 (FY 04)? If applicable, please list this statistic for each of the testing sites that are under your auspices using the name of the site and its site number.

3) What was the "return rate" for positive test results and negative test results in your organization for July 2002 through June 2003 (FY 03)? If applicable, please list this statistic for each of the testing sites that are under your auspices using the name of the site and its site number.

4) Please list your primary interests in utilizing HIV rapid testing (i.e., increasing the number or proportion of clients who receive their test results, ease of use, increasing the number/proportion of high-risk clients who choose to be tested for HIV, enhancement of a particular program, a combination of these or any other relatable reasons are also acceptable)?

5) Is your organization interested in implementing rapid HIV testing, attending the necessary training and conducting quality assurance activities? Please list below any relevant persons within your agency who have expressed an interest and have agreed to support the adoption of OraQuick ADVANCE®. ☐ Yes ☐ No

6) Will the necessary staff members be able to attend a full day training to become knowledgeable about OraQuick ADVANCE®, how to conduct OraQuick ADVANCE® testing and how to perform the required quality assurance tests? ☐ Yes ☐ No

7) Storage of and quality control for the OraQuick ADVANCE test will require adequate storage space. Does your organization have the following required items:

a storage room or closet that is climate controlled (maintains a temperature of 59 to 80 degrees F)? ☐ Yes ☐ No

a separate refrigerator to store the quality assurance kits (this refrigerator cannot be used to store food)? ☐ Yes ☐ No

If you answered "No" to question 7, can arrangements be made to accommodate storage needs that meet with the above standards? Please elaborate below.

8) Does your organization have an OSHA blood borne pathogen exposure control plan in case of an accidental blood exposure (i.e., a needle stick)? ☐ Yes ☐ No

If you answered "Yes" to question 8, does this plan include:

the use of "Safer Sharps"? ☐ Yes ☐ No
gloving and hand washing techniques? ☐ Yes ☐ No
an annual educational component? ☐ Yes ☐ No
a spill kit? ☐ Yes ☐ No
a plan for biohazard and sharps disposal? ☐ Yes ☐ No

If you answered "No" to question 8, would your organization be Interested in adopting and implementing an OSHA blood borne pathogen exposure control plan? ☐ Yes ☐ No

9) Rapid HIV testing has the potential to increase the number of HIV infected individuals who learn their HIV serostatus and who are subsequently in need of access to various services. This will require each organization to plan ahead for a possible influx of patients. Does your organization have the capacity to deal with an increased number of clients for the following services:

prevention services for those who test negative? ☐ Yes ☐ No
medical services for those who test positive? ☐ Yes ☐ No
support services for those who test positive? ☐ Yes ☐ No

If you answered "No" to any part of question 9, does your organization have the ability to make referrals for these services? Please list the provider(s) you will refer to and the service(s) they provide. □ Yes □ No

10) Will HIV rapid testing be used in all of the CTR settings within your organization (i.e., STD clinics, family planning clinics, addiction services, etc.)? □ Yes □ No

Please elaborate on which specific programs within your organization that OraQuick ADVANCE® may be better suited for than others (please include their site numbers).

11) Are there some sites within your organization that are currently collecting blood for other diseases (i.e., STD's or Hepatitis B and C)? □ Yes □ No

Is it practical for those sites to offer rapid testing if bloods are already being drawn for other purposes? □ Yes □ No □ N/A

12) The process for the rapid testing will consist of time for taking an oral swab or a finger stick or venipucture, development of the results for no less than 20 minutes and no more than 40 minutes, and delivery of results. There may be some time while the results are developing to complete paperwork or administer other services. Will this process interfere with any other services that must be accessed for clients (i.e., family planning clinics, STD clinics, addiction services)? □ Yes □ No

Can these clinics/services be altered to accommodate the time needed to complete the rapid test? Please elaborate below. □ Yes □ No

13) The OraQuick ADVANCE® Rapid HIV-1/2 Anti-body Test is a screening test a (ELISA) that will require confirmatory test (Western Blot). Do you have a process in your organization to obtain a confirmatory blood specimen (i.e. Do you refer clients for care)? □ Yes □ No

If you answered "Yes" to question 13, please give a brief description of the process (i.e. Where do you refer clients for care?).

If you answered "No" to question 13, could arrangements be made for this? What would those arrangements be? ☐ Yes ☐ No

14) Please list any other issues that you feel are pertinent with regards to HIV rapid testing and your organization. Include in this section any benefits or concerns you may have that you anticipate occurring with the implementation of this technology.

15) There may be additional costs associated with offering OraQuick ADVANCE® that your agency must consider and ensure they have the ability to cover. The AIDS Administration will provide technical assistance and several of the needed supplies to get your program started, but you may be expected to cover the future expense of the supplies at some point. Does your agency have the capability to cover the expenses for supplies? ☐ Yes ☐ No